



1642  
\$

Patent Docket P1085R3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of  Vanessa Hsei et al.  Serial No.: 09/355,014  Filed: July 21, 1999  For: ANTIBODY FRAGMENT- POLYMER CONJUGATES AND HUMANIZED ANTI-IL-8 MONOCLONAL ANTIBODIES	Group Art Unit: 1642  Examiner: L. Helms  <div>CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on  March 2, 2001  Yvonne Carter</div>
--	--

#7

RECEIVED  
MAR 2 1 2001  
TECH-CENTER 1600/2900

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This application is related to co-pending application U.S. Serial No. 08/804,444 filed February 21, 1997, now granted as U.S. Pat. No. 6,117,980, co-pending application U.S. Serial No. 09/012,116 filed January 22, 1998, now abandoned, co-pending application U.S. Serial No. 09/026,985 filed February 20, 1998, now granted as U.S. Pat. No. 6,133,426, co-pending application U.S. Serial No. 09/027,449 filed February 20, 1998, now granted as U.S. Pat. No. 6,025,158, co-pending application U.S. Serial No. 09/121,952 filed July 24, 1998, co-pending application U.S. Serial No. 09/122,513 filed July 24, 1998, now abandoned, co-pending application U.S. Serial No. 09/234,340 filed January 20, 1999, co-pending application U.S. Serial No. 09/234,182 filed January 20, 1999, co-pending application U.S. Serial No. 09/726,258 filed November 29, 2000, co-pending application U.S. Serial No. 09/254,909 filed March 16, 1999, and co-pending application U.S. Ser. No. 09/489,394 filed January 21, 2000.

On or about May 21-25, 1995, a poster entitled "Site-Specific Coupling of

05/10/2001 14:00:00  
05/10/2001 14:00:00

Monomethoxypoly(ethylene glycol) to a Single-Sulfhydryl Humanized Fab" naming as authors Gerardo Zapata, Dorothy Bates, Monika Schoenhoff, Jim Deveney, Steve Frie, Brad Snedecor, Paul Carter and Steven M. Chamow was presented at a poster session of the American Society for Biochemistry and Molecular Biology FASEB Meeting held on May 21-25, 1995. All of the information that was disclosed in the aforementioned poster is contained in a 27 page reproduction of the poster enclosed with the present Information Disclosure Statement.

On February 23, 1997, a poster entitled "Humanization of Murine 6G425: An Anti-IL-8 Monoclonal Antibody which Blocks Binding of IL-8 to Human Neutrophils" naming as authors Tania N. Gonzalez, Steven R. Leong, Rhona Kabakoff, Caroline Hebert and Leonard G. Presta was presented at a poster session of the 1996 Keystone Symposia on Exploring and Exploiting Antibody and Ig Superfamily Combining Sites held on February 23-24, 1996. All of the information that was disclosed in the aforementioned poster is contained in a 21 page reproduction of the poster enclosed with the present Information Disclosure Statement.

On or about July 25-29, 1998, an abstract entitled "Tailoring Antibody Fragments with PEGylation without Loss in Biological Activity" naming as authors Iphigenia L. Koumenis, Gerardo Zapata, Steve Leong, Vanessa Hsei and Zahra Shahrokh was presented at The Protein Society 12th Symposium held on July 25-29, 1998. The abstract was published in Protein Science, 7(Suppl. 1):73 (July, 1998), Abstract #109-M, a copy of which is enclosed with the present Information Disclosure Statement.

This Information Disclosure Statement is filed in accordance with the provisions of:

[x] **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

[] **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

[] **37 CFR §1.97(d)**

- after the period specified in 37 CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

☐ **BLAST results enclosed:**

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☐ not given

☐ given for each listed item

☒ given for only non-English language listed item(s) [Required]

For item number 32 (WO 96/02576), an English abstract is attached.

For item number 39 (WO 97/40215), an English abstract is attached.

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

Date: March 8, 2001

By: Richard B. Love

Richard B. Love

Reg. No. 34,659

Telephone No. (650) 225-5530



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1085R3

Serial No.

09/355,014

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Hsei et al.

Filing Date

21 Jul 1999

Group

1642

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	1	4,002,531	11.01.77	Royer			
	2	4,179,337	18.12.79	Davis et al.			
	3	4,732,863	22.03.88	Tomasi et al.			
	4	5,147,537	15.09.92	Sada et al.			
	5	5,166,322	24.11.92	Shaw et al.			
	6	5,169,627	08.12.92	Cunningham-Rundles			
	7	5,527,528	18.06.96	Allen et al.			
	8	5,532,150	02.07.96	Snow et al.			
	9	5,595,732	21.01.97	Hakini et al.			
	10	5,620,689	15.04.97	Allen et al.			
	11	5,643,575	01.07.97	Martinez et al.			
	12	5,661,020	26.08.97	Snow et al.			
	13	5,670,132	23.09.97	Griffiths et al.			
	14	5,677,426	14.10.97	Fong et al.			
	15	5,679,532	21.10.97	Repine, J.			
	16	5,686,070	11.11.97	Doerschuk et al.			
	17	5,695,760	09.12.97	Faanes et al.			
	18	5,698,196	16.12.97	Matsushima et al.			
	19	5,702,946	30.12.97	Doerschuk et al.			
	20	5,707,622	13.01.98	Fong et al.			
	21	5,766,897	16.06.98	Braxton, S.			
	22	5,874,080	23.02.99	Hebert et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	23	770,628	02.05.97	EPO				
	24	WO 92/04372	19.03.92	PCT				
	25	WO 94/12219	09.06.94	PCT				
	26	WO 94/21235	29.09.94	PCT				
	27	WO 95/11987	04.05.95	PCT				
	28	WO 95/15769	15.06.95	PCT				
	29	WO 95/23813	08.09.95	PCT				
	30	WO 95/23865	08.09.95	PCT				
	31	WO 95/32003	30.11.95	PCT				
	32	WO 96/02576	01.02.96	PCT (ENGLISH ABSTRACT ATTACHED)				
	33	WO 96/09325	28.03.96	PCT				

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1085R3

Serial No.

09/355,014

## LIST OF DISCLOSURES GIVEN BY APPLICANT

(Use several sheets if necessary)

Applicant

Hsei et al.

Filing Date

21 Jul 1999

Group

1642

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	34	WO 96/22785	01.08.96	PCT				
	35	WO 96/34015	31.10.96	PCT				
	36	WO 96/40731	19.12.96	PCT				
	37	WO 97/01354	16.01.97	PCT				
	38	WO 97/10847	27.03.97	PCT				
	39	WO 97/40215	30.10.97	PCT (ENGLISH ABSTRACT ATTACHED)				
	40	WO 98/25971	18.06.98	PCT				
	41	WO 98/37200	27.08.98	PCT				
	42	WO 99/37779	29.07.99	PCT				

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	43	Abuchowski and Davis, "Soluble Polymer- Enzyme Adducts" <u>Enzymes as Drugs</u> , Holcenberg, JS; Roberts, J eds., New York:Wiley, Chapter 13, pps. 367-383 (1981)
	44	Adagen Label <u>Physicians' Desk Reference</u> (Product Information), 48 edition, Montvale, NJ:Medical Economics Data Production Company pps. 917-918 (1994)
	45	Allen et al., "A new strategy for attachment of antibodies to sterically stabilized liposomes resulting in efficient targeting to cancer cells" <u>Biochimica et Biophysica Acta</u> 1237(2):99-108 (Jul 26, 1995)
	46	Anderson and Tomasi, "Polymer modification of antibody to eliminate immune complex and Fc binding" <u>Journal of Immunological Methods</u> 109(1):37-42 (Apr 22, 1988)
	47	Beauchamp et al., "A new procedure for the synthesis of polyethylene glycol-protein adducts; effects on function, receptor recognition, and clearance of superoxide dismutase, lactoferrin, and $\alpha_2$ -macroglobulin" <u>Analytical Biochemistry</u> 131(1):25-33 (1983)
	48	Bernard et al., "The American-European Consensus Conference on ARDS. Definitions, mechanisms, relevant outcomes, and clinical trial coordination" <u>American Journal of Respiratory &amp; Critical Care Medicine</u> 149(3 Pt 1):818-824 (Mar 1994)
	49	Brooks and Stocks, "Use of polyacrylamide-derivatized antibody in dextran-poly(ethylene glycol) systems" <u>Methods in Enzymology</u> 228:390-395 (1994)
	50	Brumeanu et al., "Derivatization with monomethoxypolyethylene glycol of Igs expressing viral epitopes obviates adjuvant requirements" <u>Journal of Immunology</u> 154(7):3088-3095 (Apr 1, 1995)
	51	Carter et al., "Preparation and uses of Fab' fragments from Escherichia coli" <u>Antibody Engineering: a Practical Approach</u> , Hoogenboom, H., McCafferty, J., Chiswell, D. eds., Oxford, UK: IRL Press, Chapter 13, pps. 291-308 (1996)
	52	Chamow et al., "Modification of CD4 immunoadhesin with monomethoxypoly(ethylene glycol) aldehyde via reductive alkylation" <u>Bioconjugate Chemistry</u> 5(2):133-140 (Mar-Apr 1994)
	53	Chapman et al., "Therapeutic antibody fragments with prolonged in vivo half-lives" <u>Nature Biotechnology</u> 17(8):780-783 (Aug 1999)
	54	Clark et al., "Long-acting growth hormones produced by conjugation with polyethylene glycol" <u>Journal of Biological Chemistry</u> 271(36):21969-21977 (Sep. 6, 1996)
	55	Cunningham-Rundles et al., "Biological activities of polyethylene-glycol immunoglobulin conjugates. Resistance to enzymatic degradation" <u>Journal of Immunological Methods</u> 152(2):177-190 (Aug 10, 1992)
	56	Davis et al., "Soluble, Nonantigenic Polyethylene Glycol-Bound Enzymes" <u>Biomedical Polymers: Polymeric Materials and Pharmaceuticals for Biomedical Use</u> , Goldberg, E and Nakajima, A eds., New York:Academic Press pps. 441-452 (1980)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1085R3

Serial No.

09/355,014

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Hsei et al.

Filing Date

21 Jul 1999

Group

1642

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 57 Delgado et al., "Analytical partitioning of poly(ethylene glycol)-modified proteins" Journal of Chromatography B 692(2):263-272 (May 9, 1997)
- 58 Delgado et al., "Distinct Influence of PEGylation on the Tumour Localisation of Transferrin and a Tumour-Specific Fab Fragment (F9)" Journal of Cellular Biochemistry (Abstr. A4-101, Keystone Symposium held at Hilton Head Island, SC, Jan 7-13 1995) Suppl. 19A:171 (1995)
- 59 Delgado et al., "Enhanced tumour specificity of an anti-carcinoembryonic antigen Fab' fragment by poly(ethylene glycol) (PEG) modification" British Journal of Cancer 73(2):175-182 (Jan 1996)
- 60 Delgado et al., "The uses and properties of PEG-linked proteins" Critical Reviews in Therapeutic Drug Carrier Systems 9(3-4):249-304 (1992)
- 61 Deuel et al., "Amino acid sequence of human platelet factor 4" Proc. Natl. Acad. Sci. 74:2256-2258 (1977)
- 62 Donnelly et al., "Interleukin-8 and development of adult respiratory distress syndrome in at-risk patient groups" Lancet 341(8846):643-647 (Mar 13, 1993)
- 63 Elling and Kula, "Immunoaffinity partitioning: synthesis and use of polyethylene glycol-oxirane for coupling to bovine serum albumin and monoclonal antibodies" Biotechnology and Applied Biochemistry 13(3):354-362 (Jun 1991)
- 64 Eno-Amooquaye et al., "Altered biodistribution of an antibody-enzyme conjugate modified with polyethylene glycol" British Journal of Cancer 73(11):1323-1327 (Jun 1996)
- 65 Folkesson et al., "Acid aspiration-induced lung injury in rabbits is mediated by interleukin-8-dependent mechanisms" Journal of Clinical Investigation 96(1):107-116 (Jul 1995)
- 66 Gonzalez et al., "Humanization of Murine 6G425: An Anti-IL8 Monoclonal Antibody Which Blocks Binding of IL8 to Human Neutrophils" 1996 Keystone Symposia on Exploring and Exploiting Antibody and Ig Superfamily Combining Sites (Poster) pps. 1-21 (February 1996)
- 67 Harding et al., "Immunogenicity and pharmacokinetic attributes of poly(ethylene glycol)-grafted immunoliposomes" Biochimica et Biophysica Acta 1327(2):181-192 (Jul 25, 1997)
- 68 Harris et al., "Synthesis and Characterization of Poly(ethylene Glycol) Derivatives" J. Polym. Sci., Polym. Chem. Ed. 22(2):341-352 (1984)
- 69 Haselgrubler et al., "Synthesis and applications of a new poly(ethylene glycol) derivative for the crosslinking of amines with thiols" Bioconjugate Chemistry 6(3):242-248 (May-Jun 1995)
- 70 Hebert et al., "Endothelial and Leukocyte Forms of IL-8: Conversion by Thrombin and Interactions with Neutrophils" J. Immunol. 145(9):3033-3040 (Nov 1, 1990)
- 71 Hebert et al., "Interleukin-8: A Review" Cancer Investigation 11(6):743-750 (1993)
- 72 Hebert, C., "Humanized anti IL-8 antibodies: potential therapy for shock and ARDS?" (Summary of seminar presented at the 1997 Keystone Symposia on "The Role of Chemokines in Leukocyte Trafficking and Disease" held at the Copper Mountain Resort, CO on March 31-April 5, 1997.) pps. 4
- 73 Karr et al., "Use of poly(ethylene glycol)-modified antibody in cell extraction" Methods in Enzymology 228:377-390 (1994)
- 74 Katre N., "The Conjugation of Proteins with Polyethylene Glycol and other Polymers. Altering properties of proteins to enhance their therapeutic potential." Advanced Drug Delivery Reviews 10(1):91-114 (1993)
- 75 Kawamura et al., "Immune responses to polyethylene glycol modified L-asparaginase in mice" International Archives of Allergy & Applied Immunology 76(4):324-330 (1985)
- 76 Kirpotin et al., "Sterically stabilized anti-HER2 immunoliposomes: design and targeting to human breast cancer cells in vitro" Biochemistry 36(1):66-75 (Jan 7, 1997)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1085R3

Serial No.

09/355,014

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Hsei et al.

Filing Date

21 Jul 1999

Group

1642

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- |    |  |
|----|--|
| 77 | Kitamura et al., "Chemical engineering of the monoclonal antibody A7 by polyethylene glycol for targeting cancer chemotherapy" <u>Cancer Research</u> 51(16):4310-4315 (Aug 15, 1991)  |
| 78 | Kitamura et al., "Polyethylene glycol modification of the monoclonal antibody A7 enhances its tumor localization" <u>Biochemical &amp; Biophysical Research Communications</u> 171(3):1387-1394 (Sep 28, 1990)   |
| 79 | Knauf et al., "Relationship of Effective Molecular Size to Systemic Clearance in Rats of Recombinant Interleukin-2 Chemically Modified with Water Soluble Polymers" <u>The Journal of Biological Chemistry</u> 263(29):15064-15070 (Oct 15, 1988)                |
| 80 | Ko et al., "A sensitive enzyme-linked immunosorbent assay for human interleukin-8" <u>J. Immunol. Methods</u> 149:227-235 (1992)   |
| 81 | Koumenis et al., "Tailoring antibody fragments with PEGylation without loss in biological activity" <u>Protein Science</u> (Abstract 109-M, presented at the Protein Society's Twelfth Symposium in San Diego, CA on July 25-29, 1998) 7(Suppl. 1):73 (Jul 1998) |
| 82 | Lang et al., "Suppression of antibody responses in rats to murine anti-CD4 monoclonal antibodies by conjugates with monomethoxypolyethylene glycol" <u>Immunology Letters</u> 32(3):247-252 (May 1992)   |
| 83 | Lee and Sehon, "Suppression of reagenic antibodies with modified allergens. I. Reduction in allergenicity of protein allergens by conjugation to polyethylene glycol" <u>International Archives of Allergy &amp; Applied Immunology</u> 56(2):159-170 (1978)     |
| 84 | Mainolfi, E. et al., "Reduction of Immunogenicity of A Murine ANTI-ICAM-1 Antibody Through Pegylation Chemistry" <u>The 9th International Congress of Immunology (abstract book)</u> (abstract #5247) pps. 885 (1995)  |
| 85 | Maiti et al., "Tolerogenic conjugates of xenogeneic monoclonal antibodies with monomethoxypolyethylene glycol. I. Induction of long-lasting tolerance to xenogeneic monoclonal antibodies" <u>International Journal of Cancer Suppl.</u> 3:17-22 (1988)          |
| 86 | Maruyama et al., "Immunoliposomes bearing polyethyleneglycol-coupled Fab' fragment show prolonged circulation time and high extravasation into targeted solid tumors in vivo" <u>FEBS Letters</u> 413(1):177-180 (Aug 11, 1997)                                  |
| 87 | Maruyama et al., "Targeting efficiency of PEG-immunoliposome-conjugated antibodies at PEG terminals" <u>Advanced Drug Delivery Reviews</u> 24:235-242 (1997)   |
| 88 | Matsumoto et al., "Prevention of cerebral edema and infarct in cerebral reperfusion injury by an antibody to interleukin-8" <u>Laboratory Investigation</u> 77(2):119-125 (Aug 1997)   |
| 89 | Mulligan et al., "Inhibition of Lung Inflammatory Reactions in Rats by an Anti-Human IL-8 Antibody" <u>J. Immunol.</u> 150(12):5585-5595 (June 15, 1993)   |
| 90 | Nordvall et al., "IgG and IgE antibody patterns after immunotherapy with monomethoxy polyethyleneglycol modified honey bee venom" <u>Allergy: European Journal of Allergy &amp; Clinical Immunology</u> 41(2):89-94 (Feb 1986)                                   |
| 91 | Pedley et al., "The potential for enhanced tumour localisation by poly(ethylene glycol) modification of anti-CEA antibody" <u>British Journal of Cancer</u> 70(6):1126-1130 (Dec 1994)   |
| 92 | Sekido et al., "Prevention of lung reperfusion injury in rabbits by a monoclonal antibody against interleukin-8" <u>Nature</u> 365:654-657 (October 14, 1993)  |
| 93 | Shahinian and Silvis, "A novel strategy affords high-yield coupling of antibody Fab' fragments to liposomes" <u>Biochimica et Biophysica Acta</u> 1239(2):157-167 (Nov 1, 1995)  |
| 94 | Sharp et al., "Synthesis and application of a poly(ethylene glycol)-antibody affinity ligand for cell separations in aqueous polymer two-phase systems" <u>Analytical Biochemistry</u> 154(1):110-117 (Apr 1986)   |
| 95 | (Shearwater Polymers, Inc.'s January 1996 Catalog of Polyethylene Glycol Derivatives) pps. 1-50  |
| 96 | St. John et al., "Immunologic Therapy for ARDS, Septic Shock, and Multiple-Organ Failure" <u>Chest</u> 103:932-943 (1993)  |

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.





FORM P-1049

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P1085R3

Serial No.

09/355,014

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Hsei et al.

Filing Date

21 Jul 1999

Group

1642

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- |     |   |
|-----|---|
| 97  | Sticherling et al., "Immunohistochemical studies on NAP-1/IL-8 in contact eczema and atopic dermatitis" <u>Arch. Dermatol. Res.</u> 284:82-85 (1992)  |
| 98  | Sticherling et al., "Production and Characterization of Monoclonal Antibodies Against the Novel Neutrophil Activating Peptide NAP/IL-8" <u>J. Immunol.</u> 143(5):1628-1634 (September 1, 1989)   |
| 99  | Suzuki et al., "Physicochemical and biological properties of poly(ethylene glycol)-coupled immunoglobulin G. Part II. Effect of molecular weight of poly(ethylene glycol)" <u>Journal of Biomaterials Science, Polymer Edition</u> 1(2):71-84 (1989)  |
| 100 | Suzuki et al., "Preparation and characteristics of magnetite-labelled antibody with the use of poly(ethylene glycol) derivatives" <u>Biotechnology &amp; Applied Biochemistry</u> 21(Pt 3):335-345 (Jun 1995)   |
| 101 | Tanaka et al., "Synthesis and biological characterization of monocyte-derived neutrophil chemotactic factor" <u>FEBS letters</u> 236(2):467-470 (Aug 1988)  |
| 102 | Van Damme et al., "Purification of granulocyte chemotactic peptide/interleukin-8 reveals N-terminal sequence heterogeneity similar to that of $\beta$ -thromboglobulin" <u>European Journal of Biochemistry</u> 181:337-344 (1989)  |
| 103 | Veronese et al., "Improvement of pharmacokinetic, immunological and stability properties of asparaginase by conjugation to linear and branched monomethoxy poly(ethylene glycol)" <u>Journal of Controlled Release</u> 40:199-209 (1996)  |
| 104 | Wie et al., "Suppression of reaginic antibodies with modified allergens. III. Preparation of tolerogenic conjugates of common allergens with monomethoxypolyethylene glycols of different molecular weights by the mixed anhydride method" <u>International Archives of Allergy &amp; Applied Immunology</u> 64(1):84-99 (1981) |
| 105 | Yokoi et al., "Prevention of endotoxemia-induced acute respiratory distress syndrome-like lung injury in rabbits by a monoclonal antibody to IL-8" <u>Laboratory Investigation</u> 76(3):375-384 (Mar 1997)   |
| 106 | Yoshimoto et al., "Chemical modification of tryptophanase from E. coli with polyethylene glycol to reduce its immunoreactivity towards anti-tryptophanase antibodies" <u>Enzyme</u> 36(4):261-265 (1986)  |
| 107 | Yoshimura et al., "Neutrophil attractant/activation protein-1 and monocyte chemoattractant protein-1 in rabbit. cDNA cloning and their expression in spleen cells" <u>J. Immunol.</u> 146:3483-3488 (1991)  |
| 108 | Zapata et al., "Site-Specific Coupling of Monomethoxypoly(ethylene glycol) to a Single-Sulfhydryl Humanized Fab'" (poster presented at the American Society for Biochemistry and Molecular Biology FASEB Meeting in San Francisco, CA on May 21-25, 1995) pps. 1-27   |
| 109 | Zapata et al., "Site-Specific Coupling of Monomethoxypoly(ethylene glycol) to a Single-Sulfhydryl Humanized Fab'" <u>FASEB Journal</u> (Abstract #1288, presented at the American Society for Biochemistry and Molecular Biology FASEB Meeting in San Francisco, CA on May 21-25, 1995) 9(6):A1479 (1995)                       |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |
|     |   |

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.